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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/544,984 04/07/00 KLEIN

P 44033-093

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WASHINGTON DC 20005

HM12/0705

EXAMINER

BAHAR, M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/544,984

Applicant(s)

KLEIN ET AL.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-46 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 29-36, drawn to a therapeutic compound and a pharmaceutical composition of formula I, classified in class 514, subclasses 222.5, 223.8, 229.2, 258 and 263, or class 534 subclass 560, for example.
- II. Claims 19-23 and 37-41, drawn to a method of inhibiting a cellular process or activity mediated by IL-12, classified in class 514, subclasses 222.5, 223.8, 229.2, 258 and 263, for example.
- III. Claims 24-28 and 42-46, drawn to a method of treating a Th 1 cell-mediated inflammatory response in a mammal in need of such treatment, classified in class 514, subclasses 222.5, 223.8, 229.2, 258 and 263, for example.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions since Group II is drawn to a method of inhibiting a cellular process or activity mediated by IL-12 and Group III is drawn to a method of treating a Th 1 cell-mediated inflammatory response in a mammal in need of such treatment.

Inventions I and II, III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case inflammatory diseases/disorders associated with inflammatory responses can be treated with a materially different product such as ibuprofen.

***Specie Election***

Applicant is required to elect a single compound for examination.

Claims 1-46 are generic to a plurality of disclosed patentably distinct species comprising compounds having specified substitutions on R<sub>1</sub>, R<sub>2</sub>, X, Y and Z to the core structure represented by compounds of Formula I.

These claims encompass species of formula I compounds that are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus the stated species are capable of supporting separate patents. To illustrate this diversity, consider the following examples: A compound of formula I wherein R<sub>1</sub> and R<sub>2</sub> are both Hydrogen X and Y are both NR<sub>3</sub> and Z is CR<sub>3</sub> and R<sub>3</sub> is H is classified in class 514, subclass 263. A compound of formula I wherein R<sub>1</sub> and R<sub>2</sub> are both Hydrogen X and Y and Z are CR<sub>3</sub> and R<sub>3</sub> is H is classified in class 514, subclass 258. A compound of formula I wherein R<sub>2</sub> is Hydrogen X and Y are both NR<sub>3</sub> and Z is CR<sub>3</sub> and R<sub>3</sub> is H and R<sub>1</sub> is 1,3,5-thiadiazine (a heteroaryl), is classified in class 514, subclass 223.8. A compound of formula I wherein R<sub>2</sub> is Hydrogen X and Y are both NR<sub>3</sub> and Z is CR<sub>3</sub> and R<sub>3</sub> is H and R<sub>1</sub> is thiadiazine (a heteroaryl containing 2 Nitrogens and 1 Sulfur other than 1,3,5-thiadiazine), is classified in class 514, subclass 229.2. A compound of formula I wherein R<sub>2</sub> is Hydrogen X and Y are both NR<sub>3</sub> and Z is CR<sub>3</sub> and R<sub>3</sub> is H and R<sub>1</sub> is a 6 membered heteroaryl containing 2 Nitrogens and 1 Oxygen, is classified in class 514, subclass 229.2.

If applicant elects the invention of Group II or III a further election of species is required.

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This application contains claims directed to the following patentably distinct species of disorders associated with inflammatory response: chronic inflammatory disease, chronic intestinal inflammation, arthritis, psoriasis, asthma, and many different autoimmune disorders such as type 1-IDDM, multiple sclerosis, rheumatoid arthritis, uveitis, inflammatory bowel disease, lupus disorders, acute and chronic graft-versus host disease. The treatment of each disorders associated with inflammatory response represents a separate field of medical technology having a separate, non-coextensive field of search. The treatment for asthma differs from that of multiple sclerosis. Similarly, the treatment of arthritis is not the same as the treatment of inflammatory bowel disorder. The search for all the disorders/conditions encompassed by disorders associated with inflammatory response above is therefore an undue burden on the office. Note that the search is not limited to the patent files.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 are generic.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The

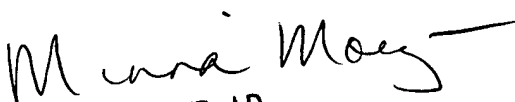
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examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
June 27, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600